

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**103948/0**

**CHEMISTRY REVIEW(S)**

05/03/01

# Review Memo

**Ref:** STN 103948

**Prepared by:** Kurt Brorson, Ph.D., Staff Scientist, DMA *KR*

**Through:** Kathryn Stein, Ph.D., Director, DMA *K.S. Stein 5/3/01*  
Keith Webber Ph.D., Deputy Director, DMA *KW*

**Sponsor:** Millenium & Ilex partners (MPI) *and*

**Product:** Campath

**Date of submission:** April 24, 2000

**Date of review:** May 2, 2001

## Background

*and*  
MPI has submitted a BLA for their anti-CD52 mAb, Campath, for use in CLL. The original BLA contained — months of drug product and drug substance stability data. In response to a CBER telephone request (May 2, 2001), MPI FAXed a 24-month update of stability data for drug product. *and*

## Conclusions

- Drug product was within specifications after 24 months of storage at 2-8°C.  
**Recommendation:** approve 24 months as an initial expiry period for Campath drug product in conjunction with 6 months expiry for drug substance.

168 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

Withheld Track Number: Chemistry- 1

**Sickafuse, Sharon**

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**From:** Brorson, Kurt  
**Sent:** Thursday, May 03, 2001 5:21 PM  
**To:** Sickafuse, Sharon  
**Subject:** RE: Today's Campath telecon

## Telecon

**Ref:** STN 103948

**Prepared by:** Kurt Brorson, Ph.D., Staff Scientist, DMA

**CBER:** Kurt Brorson, Ph.D., Staff Scientist, DMA  
Kathryn Stein, Ph.D., Director, DMA  
Keith Webber Ph.D., Deputy Director, DMA

**Sponsor:** Millenium & ILEX Partners (M&I)- Robert Petrusko

**Product:** Campath

**Date:** May 3, 2001, 11:00 AM

### background

M&I has submitted a BLA for their anti-CD52 mAb, Campath, for use in CLL. The original BLA contained proposed specifications for drug product and drug substance, including potency, % monomer (HPLC) and protein A.

### Conclusions

- CBER requested a commitment from M&I to revise drug product specifications for potency, and % monomer (HPLC) and drug substance specifications for potency, % monomer (HPLC) and protein A after analysis of release data for \_\_\_\_\_ worth of commercial lots, which ever came first. M&I agreed to submit a formal letter of commitment.
- CBER noted that a \_\_\_\_\_ expiry period for \_\_\_\_\_ storage could not be granted by the agency because M&I didn't conduct a formal study examining the stability of drug product after \_\_\_\_\_ storage of drug substance.